



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 05-924-US)
(Formerly Case. No. AP35352.072448.0362)

In re Application of:)
)
Ralph Backhaus)
) Group Art Unit: 1651
Serial No.: 10/630,548)
) Examiner: Lankford
International Filing Date: July 30, 2003)
) Confirmation No.: 7467
For: Cardioprotective therapies based on)
enzymatic elimination of lipid peroxides)
by allene oxide synthase)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. Copies of the Journal references cited below are enclosed. These references are also listed on the enclosed PTO Form 1449.

In the judgment of the undersigned, portions of the listed references may be material to the Examiner's consideration of the presently pending claims. However, the references have not been reviewed in sufficient detail to make any other representation and, in particular, no representation is intended as to the relative relevance between references, whether cited in this or prior statements. This statement is not a representation that the listed references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. Section 102 or Section 103.

07/10/2006 HDESTA1 00000040 10630548

01 FC:1806

180.00 DP

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of a national application; within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or before the mailing date of a first Office Action on the merits. 37 C.F.R. § 1.97 (b)
- ☐ **after** three months of the filing date of a national application, or the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or **after** the mailing date of a first Office Action on the merits, but **before** the mailing date of a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), and includes (37 C.F.R. § 1.97 (c):
- ☐ the Certification under 37 C.F.R. § 1.97(e) (see “Certification” below)

OR

- ☐ the fee of \$180.00 set forth in 37 C.F.R. § 1.17(p) (see “Fees” below).
- ☐ **after** a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), but before, or simultaneously with, the payment of the issue fee, and includes the Certification under 37 C.F.R. § 1.97(e) (see “Certification” below), and the Petition Fee set forth in 37 C.F.R. § 1.17(i) (see “Fees” and “Method of Payment of Fees” below). Applicants hereby petitions for consideration of the Information Disclosure Statement submitted herewith and the accompanying references in examination of the subject patent application.

CERTIFICATION

- ☐ The **undersigned** hereby certifies that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

FEEs

☐
☒

No fee is owed by the applicant(s).

The **IDS Fee of \$180.00** under 37 C.F.R. § 1.17(p) is enclosed herewith.

METHOD OF PAYMENT OF FEES

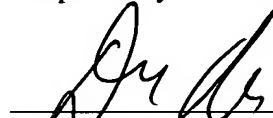
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Attached is a check in the amount of \$180.00

CERTIFICATE OF MAILING VIA EXPRESS MAIL DELIVERY under 37 C.F.R. § 1.10.

I hereby certify that the attached paper of fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to Commissioner for Patents, Box 1450, Alexandria, VA, 22313-1450, on this 6th day of July, 2006. Express Mail No. EV839406658US.

Respectfully submitted,



David S. Harper

Registration No. 42,636

U.S. Patent References:

1. Backhaus, et al., U.S. Patent No. 6,132,711, Issued on October 17, 2000.

Article References:

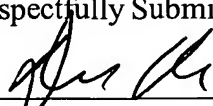
2. Abunasra, et al., (2001), European Journal of Cardio-thoracic Surgery, "Efficacy of adenoviral gene transfer with manganese superoxide dismutase and endothelial nitric oxide synthase in reducing ischemia and reperfusion injury", Vol: 20, pp. 153-158.
3. Backhaus, et al., (1997), FASEB Journal, "'Dual Roles of Allene Oxide Synthase, The Abundant Cytochrome P450 of Guayule Rubber Particles", (P35), page A776.
4. Brown, et al., (2005), JAMA, "Is There Any Hope for Vitamin E", Vol: 293(11), pp. 1387-1390.
5. Cuzzocrea, et al., (2001), "Antioxidant therapy: A new pharmacological approach in shock, inflammation, and ischemia/reperfusion injury", Pharmacol Rev., Vol: 53(1), pp. 135-159.
6. Delanty, et al., (2000), Arch Neurol, "Antioxidant Therapy in Neurologic Disease", Vol: 57, pp. 1265-1270.
7. Dhalla, et al., (2000), Cardiovascular Research, "Status of myhocardial antioxidants in ischemia-reperfusion injury", Vol: 47, pp. 446-456.
8. Flaherty, et al., (1994), Circulation, "recombinant Human Superoxide Dismutase (h-SOD) Fails to Improve Recovery of Ventricular Function in Patients Undergoing Coronary Angioplasty for Acute Myocardial Infarction", Vol:89(5), pp. 1982-1991.
9. Galang, et al., (2000), Toxicology, "Apoptotic cell death during ischemia/reperfusion and its attenuation by antioxidant therapy", Vol: 148, pp. 111-118.
10. Gladstone, et al., (2002), Stroke, "Toward Wisdom from Failure: Lessons from Neuroprotective Stroke Trials and New Therapeutic Directions", Comments, Opinion, and Reviews, Vol: 33, pp. 2123-2136.
11. Hangaishi, et al., (2001), Biochemical and Biophysical Research Communications, "Lecithinized Cu, Zn-Superoxide Dismutase Limits the Infarct Size Following Ischemia-Reperfusion Injury in Rat Hearts in Vivo", Vol: 285, pp. 1220-1225.
12. Huynh, et al., (1999), Journal of Surgical Research, "Reduction of Lipid Peroxidation with Intraoperative Superoxide Dismutase Treatment Decreases Intimal Hyperplasia in Experimental Vein Grafts", Vol: 84, pp. 223-232.

13. Kanamasa, et al., (2001), *Acta Cardiol*, "Protective effect of PEG-SOD against early coronary reperfusion injury assessed in reperfused and non-reperfused ischaemic areas of the same heart", Vol: 56, pp. 181-186.
14. Keith, et al., (2001), *Am. J. Clin. Nutr.*, "A Controlled Clinical Trial of Vitamin E Heart Failure", Vol: 73, pp. 219-224.
15. Kesavulu, et al., (2001), *Diabetes Research and Clinical Practice*, "Lipid Peroxidation and antioxidant enzyme status in Type 2 Diabetics with Coronary heart disease", Vol: 53, pp. 33-39.
16. Kilgore, et al., (1993), *Clin Biochem*, Supplementation in Patients with Congestive "Reperfusion Injury After Myocardial Infarction: The Role of Free Radicals and the Inflammatory Response", Vol: 26, pp. 359-370.
17. Kloner, et al., (1993), *JACC*, "Does Reperfusion Injury Exist in Humans", Vol: 21(2), pp. 537-545.
18. Laurindo, et al., (1991), *Circulation*, "Evidence for superoxide radical-dependent coronary vasospasm after angioplasty in intact dogs", Vol: 83, pp. 1705-1715.
19. Li Q, et al., (2001), "Gene therapy with extracellular superoxide dismutase protects conscious rabbits against myocardial infarction" *Circulation*, Vol: 103(14), pp. 1893-1898.
20. Miki, et al., (1999), *Basic Res. Cardiol*, "Failure of N-2-mercaptopropionyl glycine to reduce myocardial infarction after 3 days of reperfusion in rabbits", Vol: 94, pp. 180-187.
21. Pan Z, et al., (1998), "Aspirin inhibition and acetylation of the plant cytochrome P450, allene oxide synthase, resembles that of animal prostaglandin endoperoxide H synthase", *J. Biol. Chem.*, Vol: 273(29), pp. 18139-18145.
22. Prasad, et al., (1996), *Can J. Cardiol*, "Superoxide dismutase and catalase in protection of cardiopulmonary bypass-induced cardiac dysfunction and cellular injury", Vol: 12(10), pp. 1083-1091.
23. Rowland, et al., (1995), *Surgery*, "Mechanisms of immature myocardial tolerance to ischemia: Phenotypic differences in antioxidants, stress proteins, and oxidases", Vol: 118(2), pp. 446-452.
24. Shutenko, et al., (1999), *Biochemical Pharmacology*, "Influence of the Antioxidant Quercetin In Vivo on the Level of Nitric Oxide Determined by Electron Paramagnetic Resonance in Rat Brain during Global Ischemia and Reperfusion", Vol: 57, pp. 199-208.

25. Stranges, et al., (2006), Am. J. Epidemiol, "Effects of Selenium Supplementation on Cardiovascular Disease Incidence and Mortality: Secondary Analyses in a Randomized Clinical Trial", Vol: 163(8), pp. 694-699.
26. Tirilazad International Steering Committee, (2000), Stroke, "Tirilazad Mesylate in Acute Ischemic Stroke, A Systematic Review, Comments, Opinions, and Reviews", pp. 2257-2265.
27. Van Remmen, et al., (2001), "Knockout mice heterozygous for Sod2 show alterations in cardiac mitochondrial function and apoptosis", Am J. Physiol. Heart Circ. Physiol., Vol: 281(3), pp. H1422-H1432.
28. Venturini, et al., (1998), Journal of Thrombosis and Thrombolysis, "The Antioxiidant, N-(2-mercaptopropionyl)-glycine (MPG), Does Not Reduce Myocardial Infarct Size in an Acute Canine Model of Myocardial Ischemia and Reperfusion", Vol: 5, pp. 135-141.
29. Wall, (2000), Pharmacology "Antioxidants in Prevention of Reperfusion Damage of Vascular Endothelium", Vol: 1, pp. 67-71.
30. The HOPE and HOPE-TOO Trial Investigators, Eva Lonn, et al., (2005), JAMA, "Effects of Long-Term Vitamin E Supplementation on Cardiovascular Events and Cancer", Vol: 293(11), pp. 1338-1347.
31. Zhiqiang, et al., (1996), Plant Physiology, American Society of Plant Physiologists,"Heterologous Expression and Analysis of Allene Oxide Synthase, The Rubber-Associated P450 From Guayule", (2 Suppl), pp. 98-eoa.

In accordance with MPEP Sections 609 and 707.05(b), it is requested the document cited be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

Date: July 6, 2006

Respectfully Submitted,

By: _____
David S. Harper
Registration No. 42,636

FORM PTO-1449
(Rev. 2-32)

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

05-924-US

Serial No.

10/630,548



**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use several sheets if necessary)

Applicant: Ralph Backhaus

Filing Date:

July 30, 2003

Group:

1651

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	1.	6,132,711	17 October 2000	Backhaus, et al.			

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes No	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

2.	Abunasra, et al., (2001), European Journal of Cardio-thoracic Surgery, "Efficacy of adenoviral gene transfer with manganese superoxide dismutase and endothelial nitric oxide synthase in reducing ischemia and reperfusion injury", Vol: 20, pp. 153-158.
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